SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Iodine 2% w/v Concentrate for Teat Dip and Spray Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	**%w/v**
Available iodine	2.00
Other relevant constituents	
Glycerol	5.45
Sorbitol Solution (70% w/w)	16.35

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for Teat Dip/Teat Spray Solution
A brown liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle – milking cows

4.2 Indications for use, specifying the target species

A dilutable teat dip/spray as an aid in the control of bovine mastitis.

4.3 Contraindications

Not applicable

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

Wash and dry udders and teats before milking.
Teat dip cups should be emptied after milking and washed before re-use.
These are both important aspects of good hygiene and mastitis control.
For external use only.

ii. Special precautions for the person administering the veterinary medicinal product to animals

CONCENTRATE
The following safety phrases relate to the concentrated product only, and do not apply once the product is diluted to the working solution: Risk of serious damage to eyes. Wear eye/face protection when preparing the dip or spray.
DILUTED WORKING SOLUTION
When using as a spray, avoid working in spray mist. Avoid contact with eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. If swallowed, seek medical advice immediately and show this label. Hands and exposed skin should be washed after using this product. Do not eat, drink or smoke while using the product. Keep away from food, drink and animal feedstuffs.

iii. Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Very rare - change of active ingredient teat dip type can on very rare occasions cause skin irritation.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

The use of the product has no known interactions with other products, including cow diet supplements.
Do not mix with other chemicals.

4.9 Amount(s) to be administered and administration route

This product is diluted before use. Prepare a fresh solution daily.

Teat dipping:
Add 1 part product to 3 parts of clean water and mix well
Directly after milking each cow, dip the full length of each teat in the product.
The teat cup should be kept topped up as necessary.

Teat spraying:
Add 1 part product to 4 parts of clean water and mix well
Directly after milking each cow, spray the entire surface of each teat with the product.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable for the intended mode of application.

4.11 Withdrawal period(s)

Withdrawal period for meat/milk - zero days/hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Products for teats and udder, disinfectants

ATC Vet Code: QG52A

5.1 Pharmacodynamic properties

Iodine based teat dips have broad spectrum antibacterial action against mastitis causative organisms. The microbiological action of iodine appears to be due to an oxidative – reductive reaction involving various cell wall constituents which are irreversibly transformed. It appears sulfhydryl linkages, in bacterial cell wall components are specifically targeted by the iodine.

5.2 Pharmacokinetic properties

The absorption of iodine through the skin from teat dipping applications is well below levels which would indicate pharmokinetic activity of the type described in the committee for veterinary medicinal products summary report on iodine.

5.3 Environmental properties

Iodine based teat dips are harmful to fish and aquatic life. Ponds, watercourses or ditches must not be contaminated with the product or used containers. The impact of the active ingredient (iodine) entering the environment via normal use of the product is low

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sorbitol Solution (70% w/w)
Alcohol (C13-C15) 12 mole ethoxylate
citric acid monohydrate
sodium hydroxide
sulphuric acid (for pH adjustment)
water, deionised

6.2 Incompatibilities

Not to mix the product with other medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from direct sunlight.
Store in tightly closed original container.
Protect from frost
Discard any remaining diluted solutions at the end of the day

6.5 Nature and composition of immediate packaging

5, 25 and 200 litres natural or opaque, white or blue high density polyethylene drum with grey or white high density polyethylene or polypropylene cap (screw fit)
The 200 litre containers should not be returned for re-filling.

20 litre, blue, white or natural opaque, high density polyethylene drums, with black high density polyethylene cap (screw fit, tamper evident) with expanded polyethylene gasket.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements. To dispose of unused product to land you must have an authorisation under the Groundwater regulations 1998.

Harmful to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

Diversey Limited
Weston Favell Centre
Northampton
Northamptonshire
NN3 8PD

8. MARKETING AUTHORISATION NUMBER(S)

Vm 15985/4022

9. DATE OF FIRST AUTHORISATION

Date: 11/02/1998

10. DATE OF REVISION OF THE TEXT

Date: October 2011